CLAIMS

1. A device for treatment of urinary incontinence, comprising:

a sensor, which generates a signal responsive to a physiological characteristic indicative of a likelihood of incontinence;

a control unit, which receives the signal from the sensor; and

at least one electrode, implanted in a patient and coupled to cause contraction of a pelvic muscle of the patient responsive to application of electrical energy to the electrode, to which electrode the control unit applies an electrical waveform responsive to the signal so as to inhibit the incontinence.

2. A device according to claim 1, wherein the sensor comprises a detecting electrode, and wherein the signal comprises an electromyographic (EMG) signal generated by the detecting electrode.

3. A device according to claim 1, wherein the control unit analyzes the sensor signal to determine a time of voiding, and applies the electrical waveform at a designated time interval subsequent to the time of voiding.

4. A device according to claim 1, wherein the urinary incontinence comprises urinary urge incontinence.

5. A device according to claim 1, wherein the control unit is implanted in a vicinity of the patient's sacral spine.

6. A device according to claim 1, wherein the pelvic muscle comprises a pelvic floor muscle.

7. A device according to claim 1, wherein the electrode is implanted in a pelvic muscle of the patient.

8. A device according to claim 1, wherein the electrode comprises a single unipolar electrode.

9. A device according to claim 1, wherein the at least one electrode comprises a pair of bipolar electrodes.

10. A device according to claim 1, wherein the electrode comprises a flexible intra-muscular electrode.

11. A device according to claim 1, wherein the pelvic muscle comprises the levator ani muscle.

12. A device according to claim 1, wherein the pelvic muscle comprises the urethral sphincter muscle.

13. A device according to claim 1, wherein the pelvic muscle is adjacent to the urethral sphincter muscle.

14. A device according to claim 1, wherein the control unit receives data indicative of a fill level of the patient's bladder and, responsive to the data, does not apply the electrical waveform when the fill level of the bladder is low, even when the signal generated by the sensor is indicative of involuntary urination.

15. A device according to claim 1, wherein the sensor comprises a pressure sensor.

16. A device according to claim 1, wherein the sensor comprises an acceleration sensor.

17. A device according to claim 1, wherein the sensor comprises an ultrasound transducer.

18. A device according to claim 1, wherein the electrode is electrically coupled to a nerve which innervates the pelvic muscle.

19. A device according to claim 1 or any one of claims 3-18, wherein the sensor comprises a detecting electrode, and wherein the signal comprises an electromyographic (EMG) signal generated by the detecting electrode.

20. A device according to claim 19, wherein the control unit applies the electrical waveform responsive to an average magnitude of the EMG signal.

21. A device according to claim 20, wherein the control unit applies the waveform responsive to the average magnitude of the EMG signal exceeding a designated threshold.

22. A device according to any one of claims 1-18, wherein the at least one electrode comprises a detecting electrode, and wherein the sensor comprises the detecting electrode.

23. A device according to claim 22, and comprising a switch between the detecting electrode and an input of the control unit, which switch is opened when the electrical waveform is applied so as to prevent feedback from the detecting electrode to the input.

24. A device according to any one of claims 1-17, wherein the electrode is electrically coupled to a nerve which innervates the pelvic muscle.

25. A device according to claim 24, wherein the nerve comprises a sacral nerve.

26. A device according to any one of claims 1-18, wherein the control unit is implanted in the body of the patient.

27. A device according to claim 26, wherein the control unit comprises a rechargeable power source.

28. A device according to claim 27, wherein the power source is recharged by inductive energy transfer, substantially without requiring electrical contact between the control unit and any object outside the patient's body.

29. A device according to any one of claims 1-18, wherein the control unit comprises a processor, which analyzes the signal so as to determine when an involuntary urine flow is likely, whereupon the waveform is applied.

30. A device according to claim 29, wherein the processor analyzes the signal at a sample rate substantially greater than 1000 Hz.

31. A device according to claim 29, wherein the processor's analysis is performed on substantially non-rectified data.

32. A device according to claim 29, wherein the processor analyzes the signal using spectral analysis.

33. A device according to claim 32, wherein the spectral analysis is performed by the processor on substantially non-rectified data.

34. A device according to claim 29, wherein the processor is programmable to vary one or more parameters associated with the application of the waveform.

35. A device according to claim 34, and comprising a wireless receiver, which receives data for programming the processor from a programming unit outside the patient's body.

36. A device according to claim 29, wherein the processor comprises a first processor, which analyzes the signal substantially continuously at a low data analysis rate, and a second processor, which is actuated by the first processor to analyze the signal at a high data analysis rate when the first processor determines that involuntary urine flow is likely to occur.

37. A device according to claim 36, and comprising a queue, in which the signal is stored before the second processor is actuated, and from which queue the signal received by the control unit prior to actuation of the second processor is passed to the second processor for analysis.

38. A device according to claim 29, wherein the processor distinguishes between a signal indicative of an involuntary urine flow and a signal indicative of voluntary voiding by the patient.

39. A device according to claim 38, wherein the processor distinguishes between the signal indicative of involuntary urine flow and the signal indicative of voluntary voiding by the patient responsive to a rate of change of the signal generated by the sensor.

40. A device according to claim 38, wherein the processor gathers information regarding the signal over an extended period and analyzes the information to find a pattern characteristic of the patient, for use in determining when an involuntary urine flow is likely.

41. A device according to claim 40, wherein the pattern comprises a time-varying threshold to which a level of the signal is compared.

42. A device for treatment of urinary incontinence in a patient, comprising:

a sensor, which is coupled to generate a signal responsive to a fill level of the patient's bladder; and

a control unit, which receives and analyzes the signal so as to determine a fill level of the bladder and, responsive to the determination, applies electrical stimulation to cause the contraction of a pelvic muscle of the patient, so as to inhibit the urinary incontinence when the fill level of the bladder is above a threshold level.

43. A device according to claim 42, wherein the incontinence comprises urge incontinence.

44. A device according to claim 42, wherein the incontinence comprises stress incontinence.

45. A device according to claim 42, and comprising an electrode, which is placed in electrical contact with a nerve which innervates the pelvic muscle, wherein the stimulation comprises an electrical waveform applied to the electrode so as to stimulate the nerve to cause the muscle to contract, thereby inhibiting the incontinence.

46. A device according to claim 42, and comprising an electrode, which is placed in electrical contact with the pelvic muscle of the patient, wherein the stimulation comprises an electrical waveform applied to the electrode so as to stimulate the muscle to contract, thereby inhibiting the incontinence.

47. A device according to any one of claims 42-46, wherein the control unit receives a signal indicative of a likelihood of involuntary urination and applies the stimulation to the pelvic muscle responsive to the likelihood of involuntary urination except when the fill level of the bladder is below the threshold level.

48. A device according to claim 47, wherein the sensor comprises an electrode, which is placed in electrical contact with the pelvic muscle of the patient to receive an electromyogram signal therefrom indicative of the likelihood of involuntary urination and of the fill level.

49. A device for treatment of urinary incontinence, comprising:

at least one electrode, which is coupled to a pelvic muscle of a patient; and

a control unit, which receives electromyogram signals from the electrode indicative of possible imminent incontinence, and which determines a threshold signal level that varies over time responsive to a condition of the patient, and which, responsive to a transient increase in the electromyogram signal above the threshold level, applies an electrical waveform to stimulate the muscle to contract, so as to inhibit the incontinence.

50. A device according to claim 49, wherein the control unit applies the waveform to the electrode.

51. A device according to claim 49, and comprising a second electrode, coupled to a nerve which innervates the pelvic muscle, wherein the control unit applies the waveform to the second electrode to cause contraction of the muscle.

52. A device according to any one of claims 49-51, wherein the threshold signal level varies over time responsive to temporal variation of a mean value of the electromyogram signal.

53. A device according to any one of claims 49-51, wherein the threshold signal level increases responsive to time elapsed since the patient last passed urine.

54. A device according to any one of claims 49-51, wherein the threshold signal level increases responsive to an increase in a fill level of the patient's bladder.

55. A device for treatment of urinary incontinence, comprising:

at least one electrode, which is placed in electrical contact with a pelvic muscle of a patient; and

a control unit, which receives electromyogram signals from the electrode and, responsive to a rate of change of the signals indicative of possible imminent incontinence, applies an electrical waveform which stimulates the muscle to contract, so as to inhibit the incontinence.

56. A device according to claim 55, wherein when the rate of change is below a threshold rate, the control unit withholds the waveform, so as to allow voluntary voiding.

57. A device for treatment of urinary incontinence, comprising:

at least one electrode, which is placed in electrical contact with a pelvic muscle of a patient; and

a control unit, which receives signals indicative of impending urine flow, and distinguishes signals indicative of possible imminent incontinence from signals indicative of voluntary voiding by the patient, and responsive thereto applies an electrical waveform to the electrode which stimulates the muscle to contract, so as to inhibit incontinence.

58. A device according to claim 57, wherein the incontinence comprises urge incontinence.

59. A device according to claim 57, wherein the control unit distinguishes between the signals indicative of incontinence and the signals indicative of voluntary voiding by the patient responsive to a rate of change of the received signals.

60. A device according to any one of claims 57-59, wherein the control unit distinguishes between the signals indicative of incontinence and the signals indicative of voluntary voiding, substantially without application of an input to the control unit from outside the patient's body.

61. A device according to any one of claims 57-59, wherein the control unit gathers information regarding the signals over an extended period and analyzes the information to find a pattern characteristic of the patient, for use in determining when incontinence is likely.

62. A device according to claim 61, wherein the pattern comprises a time-varying threshold to which a level of the signals is compared.

63. A device for treatment of urinary incontinence, comprising:

at least one electrode, coupled to cause contraction of a pelvic muscle of a patient responsive to application of electrical energy to the electrode; and

a control unit, which receives at a sample rate substantially greater than 1000 Hz signals indicative of possible imminent incontinence, analyzes the signals so as to determine when the incontinence is likely, and, responsive thereto, applies an electrical waveform to the electrode which causes the muscle to contract, so as to inhibit the incontinence.

64. A device according to claim 63, wherein the incontinence comprises urge incontinence.

65. A device according to claim 63, wherein the incontinence comprises stress incontinence.

66. A device according to any one of claims 63-65, wherein the control unit analyzes the signals so as to distinguish between signals indicative of incontinence and signals indicative of voluntary voiding by the patient.

67. A device for treatment of urinary incontinence, comprising:

at least one electrode, coupled to cause contraction of a pelvic muscle of a patient responsive to application of electrical energy to the electrode;

a first processor, which receives signals indicative of a likelihood of imminent incontinence and analyzes the signals substantially continuously at a low data analysis rate; and

a second processor, which, responsive to a determination by the first processor that incontinence is imminent, is actuated by the first processor to analyze the signals at a high data analysis rate and, responsive to the analysis at the high data rate, applies an electrical waveform to the electrode which stimulates the muscle to contract, so as to inhibit the incontinence.

68. A device according to claim 67, and comprising a queue, in which the signals are stored before the second processor is actuated, and from which queue signals received by the first processor prior to actuation of the second processor are passed to the second processor for analysis.

69. A method for treatment of urinary incontinence, comprising:

coupling an electrode to cause contraction of a pelvic muscle of a patient responsive to application of electrical energy to the electrode;

receiving a signal from the patient's body indicative of impending urine flow;

analyzing the received signal to distinguish between a signal indicating that incontinence is likely and another signal indicative of voluntary voiding; and

responsive to the analysis, applying an electrical waveform to the electrode, which stimulates the muscle to contract so as to inhibit incontinence.

70. A method according to claim 69, wherein the incontinence comprises urge incontinence.

71. A method according to claim 69, wherein the incontinence comprises stress incontinence.

72. A method according to any one of claims 69-71, wherein distinguishing between the signals comprises distinguishing responsive to a rate of change of the received signal.

73. A method according to any one of claims 69-71, wherein distinguishing between the signals comprises gathering information regarding the received signal over an extended period and analyzing the information to detect a pattern characteristic of the patient, for use in determining when incontinence is likely.

74. A method according to claim 73, wherein the pattern comprises a time-varying threshold to which a level of the received signal is compared.

75. A method for treatment of urinary incontinence, comprising:

coupling an electrode to cause contraction of a pelvic muscle of a patient responsive to application of electrical energy to the electrode;

receiving at a sample rate substantially greater than 1000 Hz signals indicative of imminent urination;

analyzing the signals so as to determine when incontinence is likely; and

responsive to the analysis, applying an electrical waveform to the electrode, which stimulates the muscle to contract so as to inhibit incontinence.

76. A method according to claim 75, wherein analyzing comprises distinguishing between a signal indicating that involuntary urine flow is likely and another signal indicative of voluntary voiding.

77. A method for treatment of urinary stress incontinence of a patient, comprising:

implanting an electrode so as to cause contraction of a pelvic muscle of a patient responsive to application of electrical energy to the electrode;

receiving a signal from the patient's body indicative of imminent incontinence; and

responsive to the signal, applying an electrical waveform to the electrode, which stimulates the muscle to contract so as to inhibit incontinence.

78. A method according to claim 77, wherein the incontinence comprises urge incontinence.

79. A method according to claim 77, wherein the incontinence comprises stress incontinence.

80. A method according to claim 77, wherein implanting the electrode comprises implanting the electrode in the pelvic muscle.

81. A method according to claim 77, wherein applying the waveform comprises varying a parameter of the waveform selected from the group consisting of: amplitude, frequency, duration, wave shape and duty cycle.

82. A method according to claim 77, wherein applying the waveform comprises applying a pulse burst.

83. A method according to 77, wherein the pelvic muscle comprises the levator ani muscle.

84. A method according to claim 77, wherein the pelvic muscle comprises the urethral sphincter muscle.

85. A method according to claim 77, wherein implanting the electrode comprises implanting an electrode in proximity to the urethral sphincter muscle.

86. A method according to claim 77, wherein applying the waveform comprises applying a waveform to the electrode in a unipolar mode.

87. A method according to claim 77, wherein implanting the electrode comprises placing at least two electrodes in electrical contact with the muscle, and wherein applying the waveform comprises applying a waveform between the electrodes in a bipolar mode.

88. A method according to claim 77, wherein receiving the signal comprises receiving a signal indicative of pressure on the patient's bladder.

89. A method according to claim 77, wherein receiving the signal comprises receiving a signal indicative of motion of the patient's bladder.

90. A method according to any one of claims 77-89, wherein receiving the signal comprises receiving an electromyographic (EMG) signal.

91. A method according to claim 90, wherein applying the electrical waveform comprises applying the waveform responsive to an average magnitude of the EMG signal.

92. A method according to claim 91, wherein applying the waveform responsive to the average magnitude comprises determining whether the average magnitude of the EMG signal exceeds a designated threshold.

93. A method according to claim any one of claims 77-89, and comprising determining a time of voiding, wherein applying the electrical waveform comprises applying the waveform at a designated time interval subsequent to the time of voiding.

94. A method according to any one of claims 77-89, wherein implanting the electrode comprises coupling the electrode to a nerve which innervates the pelvic muscle.

95. A method according to claim 94, wherein the nerve comprises a sacral nerve.

96. A method according to any one of claims 77-89, and comprising receiving a signal indicative of a fill level of the patient's bladder, wherein applying the electrical waveform comprises applying a waveform responsive to the fill level.

97. A method according to claim 96, wherein applying the waveform responsive to the fill level comprises withholding application of the waveform when the fill level is low, notwithstanding the signal received indicative of abdominal stress.

98. A method according to any one of claims 77-89, wherein applying the waveform comprises analyzing the signal to determine when an involuntary urine flow is likely, and applying a waveform responsive to the determination.

99. A method according to claim 98, wherein analyzing the signal comprises analyzing substantially non-rectified data.

100. A method according to claim 98, wherein analyzing the signal comprises analyzing signals at a sample rate substantially greater than 1000 Hz.

101. A method according to claim 98, wherein analyzing the signal comprises performing a spectral analysis.

102. A method according to claim 101, wherein performing the spectral analysis comprises performing the spectral analysis on substantially non-rectified data.

103. A method according to claim 98, wherein analyzing the signal comprises distinguishing between a signal indicating that incontinence is likely and another signal indicative of voluntary voiding.

104. A method according to claim 103, wherein distinguishing between the signals comprises gathering information regarding the signals over an extended period and analyzing the information to detect a pattern characteristic of the patient, for use in determining when incontinence is likely.

105. A method according to claim 104 wherein analyzing the information comprises finding a time-varying threshold to which a level of the signals is compared.

106. A method according to claim 103, wherein distinguishing between the signals comprises distinguishing responsive to a rate of change of the signals.

107. A method for treatment of urinary incontinence, comprising:

receiving a signal indicative of a fill level of a patient's bladder, and

applying stimulation to a pelvic muscle of the patient when the fill level of the bladder is above a threshold level, so as to inhibit incontinence.

108. A method according to claim 107, wherein applying the stimulation comprises applying an electrical waveform to an electrode in contact with the pelvic muscle, thereby stimulating the muscle to contract and inhibiting incontinence.

109. A method according to claim 107, wherein receiving the signal comprises receiving a pressure signal.

110. A method according to claim 107, wherein receiving the signal comprises receiving an ultrasound signal.

111. A method according to claim 107, and comprising receiving a further signal indicative of a likelihood of imminent incontinence, wherein applying the stimulation comprises applying stimulation responsive to the likelihood of imminent incontinence except when the fill level of the bladder is below the threshold level.

112. A method according to claim 111, wherein receiving the signal comprises receiving an electromyogram signal from an electrode in contact with the pelvic muscle, wherein the signal is indicative of the likelihood of imminent incontinence and of the fill level.

113. A method for treatment of urinary incontinence, comprising:

coupling an electrode to cause contraction of a pelvic muscle of a patient responsive to application of electrical energy to the electrode;

receiving electromyogram signals from the electrode indicative of a likelihood of imminent incontinence;

determining a threshold level of the signals that varies over time responsive to a condition of the patient; and

responsive to a transient increase in the signals above the threshold level, applying an electrical waveform to the electrode which stimulates the muscle to contract, so as to inhibit incontinence.

114. A method according to claim 113, wherein determining the threshold level comprises determining a level that varies over time responsive to temporal variation of a mean value of the electromyogram signals.

115. A method according to claim 113, wherein determining the threshold level comprises increasing the threshold level responsive to time elapsed since the patient last passed urine.

116. A method according to claim 113, wherein determining the threshold level comprises increasing the threshold level responsive to an increase in a fill level of the patient's bladder.

117. A method for treatment of urinary incontinence, comprising:

coupling an electrode to cause contraction of a pelvic muscle of a patient responsive to application of electrical energy to the electrode;

receiving electromyogram signals from the electrode indicative of a likelihood of imminent incontinence;

determining a rate of change of the signals; and

responsive to the rate of change, applying an electrical waveform to the electrode which stimulates the muscle to contract, so as to inhibit incontinence.

118. A method according to claim 117, wherein applying the waveform comprises applying a waveform when the rate of change is above a threshold rate, and comprising withholding the waveform when the rate of change is below the threshold rate, so as to allow voluntary voiding.